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June 23, 2006

MEMORANDUM

TO: Administrators of Licensed Facilities and Activities

FROM: Dennis L. Gibbs, Director
Division of Health Licensing

SUBJECT: Provider-Wide Exception

In Departmental regulations requiring tuberculosis screening for designated individuals, tuberculosis infection has been diagnosed on the basis of a positive purified protein derivative (PPD)-based tuberculosis skin test (TST) result.

The Centers for Disease Control & Prevention (CDC) has recently published *Guidelines for Preventing Transmission of* Mycobacterium tuberculosis *in Health-Care Settings*, 2005 (www.cdc.gov/mmwr/PDF/rr/rr5417.pdf). The Department has reviewed this CDC tuberculosis guideline and, although a majority of tuberculosis control topics remain unchanged, there is an update relating to the PPD-based tuberculosis skin test (TST) that impacts current regulations requiring the use of a tuberculosis skin test. The guideline provides for other methods for testing individuals for tuberculosis infection.

Specifically, the CDC has approved the whole-blood interferon gamma release assay (IGRA), QuantiFERON®-TB Gold test (QFT-G) (Cellestis Limited, Carnegie, Victoria, Australia), which is a Food and Drug Administration (FDA)–approved in vitro cytokine-based assay for cell-mediated immune reactivity to *Mycobacterium tuberculosis* (*M. tuberculosis*), as a substitute for the tuberculosis skin test (TST) in tuberculosis screening programs. This IGRA is an example of a Blood Assay for *M. tuberculosis* (BAMT).

Therefore, in the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the individuals of these facilities and activities, it has been determined that an alternative standard will be considered as acceptable.

All licensed facilities and activities will be required to meet the standards outlined in the regulations regarding tuberculosis skin testing for individuals, or, as an alternative:

Where licensed facilities and activities are required to use a single-step or two-step tuberculosis skin test (TST), a single Blood Assay for M. tuberculosis (BAMT) may be substituted for the TST in the manner designated by CDC guidelines. Facilities/ Services must comply with all other elements of the licensing regulations related to tuberculosis screening, e.g., tuberculosis screening must be completed and the results must be available before any patient/resident/client/participant contact.

This exception applies to any facility or activity licensed by the Department that requires tuberculosis skin testing for individuals. This exception relates solely to SC licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions regarding the exception, please contact Randy Clark or Shelton Elliott of the Division of Health Licensing at (803) 545-4230 and specific questions concerning CDC tuberculosis guidelines or the Blood Assay for *M. tuberculosis* (BAMT), please call the Department's Division of TB Control at (803) 898-0558.

DLG/rel

cc: C. Earl Hunter, Commissioner, DHEC
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